

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	) ) ) <hr/>	
This document relates to:	) )	
Handy v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14019-RWZ	) ) )	MDL No. 02419 Docket No. 1:13-md-2419-RWZ
Armetta v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14022-RWZ	) ) )	
Torbeck v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14023-RWZ	) ) )	
Kashi v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14026-RWZ	) ) )	
Bowman v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14028-RWZ	) ) )	
Dreisch v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14029-RWZ	) ) )	
Davis v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14033-RWZ	) ) )	
Farthing v. Box Hill Surgery Center, LLC, et al. No. 1:14-cv-14036-RWZ	) ) )	

**BOX HILL DEFENDANTS' CONSOLIDATED MEMORANDUM OF LAW**  
**IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT**  
**CONCERNING PLAINTIFFS' CLAIM FOR PUNITIVE DAMAGES**

Defendants, Box Hill Surgery Center, L.L.C., Ritu T. Bhambhani, M.D., and Ritu T. Bhambhani, M.D., L.L.C. (hereinafter, collectively “Defendants” or “Box Hill Defendants”), by undersigned counsel, submit this consolidated memorandum of law in support of their motion for

summary judgment regarding Plaintiffs' claims for punitive damages in each of the Box Hill cases.

## **I. INTRODUCTION**

In each of the above captioned cases, Plaintiffs are seeking punitive damages as an element of their damages claim for each claim. The Box Hill Defendants now move for summary judgment because the undisputed facts in this matter are devoid of any support for the contention that the Box Hill Defendants acted with actual malice. Absent a showing of actual malice, Plaintiffs are precluded from recovering punitive damages as a matter of law.

The Court is well-versed on the background of these cases. Accordingly, the Defendants will refrain from restating all of the issues in these cases, which do not otherwise apply to the singular claim addressed in this motion for summary judgment.

As more fully set forth below, the Box Hill Defendants are entitled to summary judgment as to all claims for punitive damages because Plaintiffs are unable to demonstrate actual malice, which is a condition precedent to the recovery of punitive damages in a medical malpractice lawsuit.

## **II. STATEMENT OF FACTS<sup>1</sup>**

1. The Plaintiffs' alleged injuries and causes of action arise from the fungal meningitis outbreak caused by contaminated, preservative-free, methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC").<sup>2</sup>

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<sup>1</sup> The actual exhibits referenced herein are all included with and following the Statement of Undisputed Material Facts.

<sup>2</sup> Dreisch Complaint at 3, ¶ 1.

2. The tainted vials were limited to certain lots: Lot # 05212012@68 (BUD 11/17/2012); Lot # 06292012@26 (BUD 12/26/2012); and Lot # 08102912@51 (BUD 2/6/2013).<sup>3</sup> However, not all vials in all lots were actually contaminated.

3. Dr. Bhambhani administered NECC's MPA while performing epidural steroid injection procedures.<sup>4</sup> She was unaware that the MPA was contaminated.

4. Dr. Bhambhani and the Box Hill Defendants purchased preservative-free MPA from NECC because her previous employer used it, she had good results with it, and she was concerned about adverse events caused by preservatives.<sup>5</sup>

5. Similarly, thousands of health care providers across the country purchased drugs from the New England Compounding Center ("NECC") even in just the five months preceding the meningitis outbreak at issue.<sup>6</sup> Certainly, some of the same and other health care providers purchased drugs from NECC, including MPA, prior to that time as well.

6. NECC was regulated and inspected by the U.S. Food and Drug Administration ("FDA").<sup>7</sup> In a letter to Mr. Cadden and NECC dated December 4, 2006, the FDA affirmed its position that "the Federal Food, Drug, and Cosmetic Act ("FDCA") establishe[d] agency jurisdiction" over NECC.<sup>8</sup>

7. In addition to such regulatory oversight, NECC also passed the inspection of the Massachusetts Board of Registration in Pharmacy about a year prior to the outbreak, as well as an inspection by Brigham and Womens Hospital, a highly accredited and respected healthcare

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<sup>3</sup> Dreisch Complaint at 17, ¶ 51.

<sup>4</sup> Dreisch Complaint at 37, ¶ 145.

<sup>5</sup> See Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 1**.

<sup>6</sup> See NECC Customer List Since 5/21/2012, attached as **Exhibit 2**.

<sup>7</sup> See FDA Warning Letter, attached as **Exhibit 3**.

<sup>8</sup> *Id.*

institution, as recently as a week prior to the time that the first batch of recalled MPA solution was manufactured in May 2012.<sup>9</sup>

8. After receiving orders from healthcare providers like Dr. Bhambhani, NECC failed to “follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedure,” failed to take action on at least twenty-six occasions between January 2012 and September 2012 despite results from an internal environmental monitoring program that recorded bacteria and mold in the clean rooms used to produce “sterile” drug products, and distributed two lots of the recalled MPA before receiving results from sterility testing.<sup>10</sup>

9. The parties are in agreement that the applicable standard of care and professional practice did not require the Box Hill Defendants to travel to the NECC facility to perform an inspection prior to purchasing medications from NECC.<sup>11</sup>

10. On March 22, 2017, Barry Cadden, the owner and head pharmacist of NECC, was convicted by a federal jury of racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead in connection with the 2012 nationwide fungal meningitis outbreak.<sup>12</sup> As a result of his criminal conduct, Mr. Cadden was subsequently sentenced to nine years in prison.<sup>13</sup>

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<sup>9</sup> See Commonwealth of Massachusetts Inspection Report, attached as **Exhibit 4**; Brigham and Women’s Hospital Department of Pharmacy USP <797> Audit of NECC, attached as **Exhibit 5**; Brigham and Women’s Vendor Audit Survey Form, attached as **Exhibit 6**.

<sup>10</sup> Dreisch Complaint at 20, ¶ 66; *Id.* at 22, ¶ 81; *Id.* at 19, ¶ 64.

<sup>11</sup> See Deposition Transcript of Dr. Lloyd R. Saberski, 67:7–67:10, excerpts attached as **Exhibit 7**; see also Deposition Transcript of Dr. Laxmaiah Manchikanti, 104:10–105:6, excerpts attached as **Exhibit 8**.

<sup>12</sup> *Owner of New England Compounding Center Convicted of Racketeering Leading to Nationwide Fungal Meningitis Outbreak*, U.S. DEPT. OF JUSTICE (Mar. 22, 2017), <https://www.justice.gov/usao-ma/pr/owner-new-england-compounding-center-convicted-racketeering-leading-nationwide-fungal>.

<sup>13</sup> Pharmacist in meningitis outbreak that kills dozens gets 9 years in prison, BOSTON GLOBE (June 26, 2017), <https://www.bostonglobe.com/metro/2017/06/26/feds-cadden-should-pay-for-fungal-meningitis-outbreak/kwet31ZTnsT4lpq4WRzkXO/story.html>.

11. In the summer and fall of 2012, NECC failed to fulfill its duty to accurately represent the safety and quality of its products to consumer and potential consumers and, in doing so, broke the law.<sup>14</sup>

12. NECC's actions fell below the standard of care with regard to the contaminated lots of MPA.<sup>15</sup>

13. The Box Hill Defendants' procurement of medications from NECC without using patient-specific prescriptions had no effect on whether the medications received were contaminated.<sup>16</sup> Plainly stated, using patient-specific prescriptions would not have prevented Plaintiffs' injuries.<sup>17</sup>

14. The conduct of NECC, rather than the Box Hill Defendants, caused the MPA to be contaminated.<sup>18</sup>

15. NECC's actions were both the actual and proximate cause of the injuries suffered by Plaintiffs.<sup>19</sup>

### III. STANDARD OF REVIEW

A moving party is entitled to summary judgment if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c)(2). The moving party is "entitled to judgment as a matter of law" when it makes a sufficient showing on all essential elements of its case to which it has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 317–18 (1986). If the non-moving party fails to

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<sup>14</sup> See Deposition Transcript of Dr. Lloyd R. Saberski, 65:5–65:18, excerpts attached as **Exhibit 7**.

<sup>15</sup> See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

<sup>16</sup> See Deposition Transcript of Dr. Lloyd R. Saberski, 167:13–168:16, excerpts attached as **Exhibit 7**.

<sup>17</sup> See *id.*

<sup>18</sup> See *id.*, 64:7–65:1, excerpts attached as **Exhibit 7**.

<sup>19</sup> See Deposition Transcript of Dr. David Chason, 120:1–121:11, excerpts attached as **Exhibit 9**.

make a sufficient showing on an essential element of his case, on which he would bear the burden of proof at trial, summary judgment is proper. *Id.* at 322.

A nonmoving party may avert summary judgment by showing that there exist specific facts that would present a genuine issue for trial. *Id.* at 324. To establish a genuine issue of fact sufficient to warrant trial, the nonmoving party “must do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party must set forth “specific facts showing there is a genuine issue for trial.” *Anderson*, 477 U.S. at 248 (quoting FED. R. CIV. P. 56(c)(2)).

#### IV. LEGAL ARGUMENT

Plaintiffs in all of the above related actions have asserted a punitive damages claim. However, none of the allegations are sufficient to support a punitive damages claim, and there are no facts that would even give rise to one, as explained below.

While Plaintiffs may attach numerous labels to their claims for punitive damages, the actions underlying the instant cases involved the medical care of a patient by a health care provider. The Maryland Health Care Malpractice Claims Act applies and the claims in the instant cases fall under alleged medical negligence. *Supra*; see also Md. Code Ann., Cts. & Jud. Proc. Art., §§ 3-2A-01, et seq.

As it applies to these types of cases, Maryland law is clear that plaintiffs are required to show actual malice as a prerequisite to the recovery of punitive damages in medical malpractice actions. *Miller v. Schaefer*, 80 Md.App. 60, 68, 559 A.2d 813 (1988); see also *H & R Block, Inc. v. Testerman*, 275 Md. 36, 338 A.2d 48 (1975). Maryland courts have characterized actual malice as **"the performance of an act...with an evil or rancorous motive influenced by hate...to**

**deliberately and willfully injure the plaintiff."** *Miller*, 80 Md.App. 60, 69, 559 A.2d 813 (quoting *Testerman*, 275 Md. at 43, 338 A.2d 48).

While Plaintiffs in the instant actions have pleaded acts of negligence, recklessness, intentional conduct, and fraudulent conduct in trying to describe the Box Hill Defendants' actions, these superfluous allegations without more do not satisfy the prerequisites of establishing a basis for punitive damages. In fact, even with common issue discovery completed, there is no set of facts that would give rise to actual malice which Plaintiffs need to support a punitive damages claim. Specifically, Plaintiffs have not and cannot point to any evidence that establishes that Dr. Bhambhani actually acted "with an evil or rancorous motive influenced by hate... to deliberately and willfully injure" the Plaintiff patients. *See Miller* and *Testerman*, *supra*. Plaintiffs cannot simply allege fraud or recklessness, for example, to meet their burden to survive summary judgment. They need to provide facts that reach "actual malice" as outlined above.

When that definition of actual malice is taken apart, it is clear that no actual malice exists here. For example, Plaintiffs have not established that Dr. Bhambhani had an "evil or rancorous motive" when treating her patients. Rancorous is defined as with bitterness or resentment. Plaintiffs can point to no evidence that Dr. Bhambhani acted with bitterness or resentment.

Likewise, Plaintiffs can point to no actual evidence or set of facts to support a claim that Dr. Bhambhani had any kind of evil motive when treating her patients. Defendants anticipate that Plaintiffs may suggest that Dr. Bhambhani was using NECC's MPA to cut costs and make more money, which they will claim is an "evil motive." However, Defendants challenge Plaintiffs to provide any evidence whatsoever that Dr. Bhambhani was purchasing NECC's MPA because of cost. In fact, the exact opposite is true. Dr. Bhambhani testified in her deposition that she used NECC's MPA because her previous employer had used it, she had good results with it, and she

was concerned about adverse events from preservatives. *See* Deposition Transcript of Ritu T. Bhambhani, M.D., 71:25–73:16, excerpts attached as **Exhibit 10**. Cost was simply not a factor in her decision to purchase MPA from NECC and Plaintiff cannot provide any evidence to the contrary. This cost incentive theory is simply a tired remnant of claims and actions against other health care provider defendants wherein facts existed to support such a claim. Plaintiffs here are simply parroting that same claim with no facts to support it. Issues of cost simply do not apply to the Box Hill cases. Accordingly, there is no evidence to support a definition of actual malice.

Even if Plaintiffs can show evidence of an evil or rancorous motive, which they cannot, Plaintiffs certainly cannot show any facts to support that Dr. Bhambhani was influenced by hate. Defendants challenge Plaintiffs to present such evidence.

Moreover, actual malice would have required Dr. Bhambhani to act deliberately or to willfully injure her patients. Plaintiffs know that to even suggest such a thing is preposterous. There are absolutely no facts in these cases to support that Dr. Bhambhani acted to deliberately or willfully injure her patients. Again, Defendants challenge Plaintiffs to present any such evidence to support this claim.

In short, Plaintiffs' punitive damages claims defy logic. For punitive damages allegations against Dr. Bhambhani to survive and permit a recovery, one would have to believe that Dr. Bhambhani, a well-respected anesthesiologist for more than 20 years in her community decided on multiple days over the summer of 2012 that she wanted to harm (or potentially harm) all of the patients that she treated. In addition, she would have needed to make that decision while being unaware that the MPA she had been administering for years without issue was contaminated. Such a determination, given the current facts and evidence, would be an extraordinary leap to say the



least. As Plaintiffs cannot support a claim for punitive damages, Defendants are entitled to summary judgment on those claims.

## **V. CONCLUSION**

For the foregoing reasons, the Box Hill Defendants respectfully request that the Court grant its motion for summary judgment.

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

I hereby certify that on this 18th day of September 2017, I served the above Memorandum upon the Clerk of the Court, using the CM/ECF system, which then sent a notification of such filing (NEF) to all counsel of record.

/s/ Gregory K. Kirby  
Gregory K. Kirby, Esq.